K122882

OCT 18 2012

510(k) Summary for the NMI HPICC III

Date prepared: 14-September2012

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
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B. Contact

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and

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C. Device Name

Trade Name:	NMI HPICC III
Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter 21CFR§880.5970, Class II
Classification Panel:	General Hospital

D. Predicate Device(s)

Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter 21CFR§880.5970, Class II
Premarket Notification(s):	K121089, K111906

E. Device Description

The NMI HPICC III are flexible radiopaque catheters with suture wings for catheter securement, extension tubes(s) which connect to proximally located luer lock adapter(s) with two pressure activated safety valves (PASV™), available in a triple lumen configuration; a reverse tapered shaft to aid in staunching bleeding at the insertion site and a non-valved lumen for central venous pressure monitoring.

The lumens are differentiated by proximally located colored extension tube clamps and/or colored luer adaptors, which identify lumen size, if the lumen is rated for power injection the maximum power injection flow rates, and "NO CT" for non-power injectable lumens.

The NMI HPICC III is designed with the option of being used with power injectors for the administration of contrast media for imaging studies such as Computerized Tomography (CT) scans and Magnetic Resonance Imaging (MRIs).

The catheters are available as single, sterile packages with a variety of procedural accessories in standard kit configurations and as a convenience to suite specific clinical needs.

F. Intended Use

The NMI HPICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI HPICC III is 6 mL/sec.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed device has similar materials, design, components and technological characteristics as the predicate intravascular catheters.

Both the proposed NMI HPICC III and predicate devices are, in brief,

- intended for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products;
- available in multi-lumen configurations with a 6 Fr outside catheter diameter;
- rated for maximum power injector settings up to 325 psi with maximum power injection flow rate up to 6 ml/second; and
- available kitted with a range of procedural accessories for user convenience

H. Performance Data

The NMI HPICC III is substantially equivalent to predicate devices based on comparison of technological characteristics and the results of non-clinical tests which included the performance evaluation conducted in accordance with the following FDA guidance document, international standards and testing which included:

- EN ISO 10555-1:2009, *Sterile, Single use intravascular catheters – Part 1: General Requirements*
- EN ISO 10555-3:1997 COR 2002, *Sterile, Single-Use Intravascular Catheters – Part 3: Central Venous Catheters*
- FDA's "*Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters dated March 16, 1995*"
- Biocompatibility per ISO-10993-1
- Internal Product Specification Requirements
- Luer Connection / Strength
- Power Injection
- Catheter Interface Compatibility
- Central Venous Pressure Monitoring

I. Conclusion

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2012

Navilyst Medical, Incorporated
Ms. Wanda Carpinella
Director, Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K122882
Trade/Device Name: NMI HPICC III
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: September 14, 2012
Received: September 20, 2012

Dear Carpinella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K122882

Device Name: NMI HPICC III

Indications for Use:

The NMI HPICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI HPICC III is 6 mL/sec.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) 10/18/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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